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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,487	02/29/2000	YEN CHOO	PM264975	8044

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/08/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/424,487

Applicant(s)

Choo et al.

Examiner

Hope Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 15, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above, claim(s) 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6, 21
- 18) ☒ Interview Summary (PTO-413) Paper No(s). 24
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. Applicant's election without traverse of Group I (claims 1-24) in Paper No. 22 is acknowledged. It is noted that applicant requested clarification of the restriction groups and elected a specie for examination purposes. The following are the inventions found in the present application and the species listed in the claims will be examined together.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24 are drawn to a method for preparing a nucleic acid binding protein, classified in class 435, subclass 4.
- II. Claims 25-27 are drawn a method for determining the presence of a target nucleic acid, classified in class 435, subclass 6.
- III. Claims 28-30, are drawn to a nucleic acid, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the methods use different products, and have different method steps and end point.

Inventions III and Inventions I-II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can

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be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case because the product of Invention III can be used in a materially different process, for example in a hybridization assay.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. The Preliminary Amendment filed February 29, 2000 has been received and entered.

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Claim Objection

✓ 4. Claims 4-11 are objected to because the claims recite sequences without the corresponding sequence identifier.

Compliance with the sequence rules is required.

Abstract

5. The abstract is objected to because this application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b).

✓ An abstract on a separate sheet is required.

Information Disclosure Statement

6. The information disclosure statement filed on February 29, 2000 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because the items listed on the information disclosure statement are missing from the application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. A line has been drawn through all items listed on pages 1-7. In addition, the Information Disclosure statement filed December 27, 2001 does not comply because only WO 98/53058 was found in the

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application and has been considered. The remaining references listed on pages 1-2 were not found in the application. It is suggested that applicant submit these items.

Drawing

7. The Figures filed February 29, 2000 have been entered and approved.

Claim Rejections - 35 U.S.C. § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to a method for preparing a nucleic acid binding protein, however, no method steps are recited, the claims only recite a rule which defines 1 amino acid of an otherwise undefined protein. Note also that claims 2-24 relate to further rules and methods for preparing a nucleic acid binding protein of the Cys2-His2 zinc finger class with no positive method steps. Note that claim 13 recites that claims 1-3 are rules. Moreover,

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applicant's response in Paper No. 22 refers to claims as reciting rules. As the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Without setting forth any steps involved in the process/method, results in an improper definition of a process and is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Basis For Statutory Double Patenting

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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10. Claims 1-24 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 1-23 and 27 of copending Application No. 09/424,488. The claims in the instant application and the copending application have similar language, scope, wording and subject matter. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as written is confusing as the matter being sought for protection is not clearly defined. Note that the claim although directed to a method of preparing a protein, does not recite any method steps, the claim only discloses a rule which defines 1 amino acid of an otherwise undefined protein (see also claims 2-12 because they relate to further rules and methods for preparing a nucleic acid binding protein of the Cys2-His2 Zinc finger class with no positive

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method steps). In addition, the claim is indefinite because it does not produce the intended effect which is to prepare a nucleic acid binding protein as an end result. Further, the claim recites “capable of binding” which renders the claim indefinite because the use of the words “capable of” implies that there are times that binding will not occur. The words “capable of” should be replaced with “which binds or that binds” (see also claims 3 and 13 and all other claims with this language).

Claim 4 is indefinite because the claim has an improper sentence structure where it recites “a method according to claim 3, wherein **the or each** zinc finger...”.

Claims 4-12, 14 and 18 are indefinite because the claims recite the one letter amino acid codes instead of the three letter codes.

Claims 15 and 16 are indefinite because the claims recite the structures of zinc fingers as being Zif 268 for example, with a reference rather than the actual sequence.

Claims 19-22 are indefinite because the claims depend from rejected based claims.

Art of Record

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Choo et al. (WO 96/06166, February 29, 1996) would anticipate claims 1-3 and 27 under 35 U.S.C. 102(b) however, the rejection has not been applied because the protection sought by applicant is not clearly defined. For example, the methods recited in the claims have no positive method steps and only recite rules thus, a proper search cannot be performed.

Choo teach nucleic acid binding motifs for α -helical zinc finger defined as triplets, and the present application specifies overlapping quadruplets as binding motifs, such that, when read 3' to 5' on the strand of the nucleic acid, base 4 of the first quadruplet is base 1 of the second and so on. However, base 4 of the quadruplet is equivalent to the 5' base of the zinc finger binding triplet defined by Choo (see page 3, line 23 to page 4 line 5 of the reference). In addition, the rules which relate to amino acids of an α -helix to corresponding bases in the bound DNA triplet or quadruplet are taught by Choo. Further, Choo teaches a recognition code for amino acid base contacts in interactions of an α -helical zinc finger nucleic acid binding motif with DNA triplets. Moreover, the reference teaches that position +2 is able to specify the base directly 3' of the cognate triplet and can thus work in conjunction with position +6 of the preceding finger, which renders the claimed invention as anticipated (see Table 2, page 35, lines 9-28 and page 4 lines 2-5). Choo also teach that if base 4 (which is equivalent to 5' base in Choo) is G then position +6 in the α -helix is Arg; or position +6 is Ser or Thr and position ++2 is Asp and also if base 4 is T, then position +6 in the α -helix is Ser or Thr and position ++2 is Asp. Therefore, the rules recited in claims 2 and 3 are taught by Choo. Additionally, Choo teaches that if base 3 (which is equivalent to the middle base of the Choo reference) is G, then position +3 in the α -helix is His, if

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base 3 is A, then position +3 is A, then position +3 in the α -helix is Asn and thus, the rules recited in claim 3 item (e)-(l) are anticipated (see Table 2). The design of the protein has no limiting scope on the protein, consequently, is taught by the Choo reference. Further, nucleic acid binding proteins, nucleic acids encoding them and transformed host cells are also taught by the reference.

Conclusion

13. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.


Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response.

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The faxing of such papers must conform with the notice published in the Official Gazette, 1096
OG (November 15, 1989).

Hope A. Robinson, MS 

Patent Examiner


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